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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ^{6} :
A61F 2/28, 2/32 // A61L 27/00

A1

(11) International Publication Number: **WO 98/12994**

(43) International Publication Date: 2 April 1998 (02.04.98)

(21) International Application Number: PCT/SE97/01597

(22) International Filing Date: 23 September 1997 (23.09.97)

(30) Priority Data:
9603540-7 27 September 1996 (27.09.96) SE

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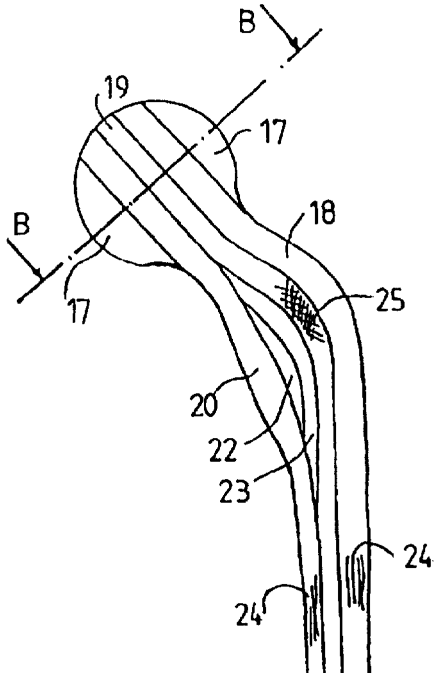
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
In English translation (filed in Swedish).

(54) Title: ORTHOPEDIC DEVICE

(57) Abstract

The present invention relates to load-carrying prosthetic devices for human implantation which are manufactured of a biocompatible fiber-reinforced matrix, e.g. polymer matrix. Furthermore, the present invention relates to processes for manufacturing such a prosthetic device. The prosthetic device is characterized in that the body is made as a solid unit, composed of a plurality of separately manufactured subelements and that the subelements of the body comprise fibers in a polymer matrix, the fibers in each subelement being independently oriented in relation to the fibers in other subelements to provide each subelement with a predetermined strength characteristic.



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Orthopedic device

The present invention relates to load-bearing prosthetic devices for human implantation which are manufactured of a biocompatible fiber-reinforced matrix, e.g. a polymer matrix. Furthermore the present invention relates to processes for manufacturing such a prosthetic device.

For various medical reasons, a large number of treatments are carried out where the body's natural joints are replaced by artificial joints, for example in hip joint operations. Load-bearing implants, such as hip joint implants of which routine medical use is made, are manufactured of metal alloys. The great difference in elastic properties between these metal implants and the surrounding bone creates problems, however. The bone tissue has a substantially lower modulus of elasticity than the metal alloys used for the implant. This results in an undesirable distribution of stresses in the bone in which the implant is fixed. A particular problem is the portions with too little stress. which inhibits bone growth and gradually weakens the bone. This can eventually result in the implant loosening from its site. By manufacturing the implant in fiber-reinforced composite material, the elastic properties of which are more compatible with the bone, it is possible to increase the life of the artificial joint.

US-A-5 141 521 describes such a prosthetic device and a method for manufacturing the same. The prosthetic device is essentially constructed about two shell halves which are made by winding individual fibers on a geometrically adapted form. The shell halves are then joined together and filled with foam or liquid material which forms a core. With this device it can, however, be difficult to achieve the required strength in the prosthesis. Furthermore, problems arise with interlaminar shear stresses since there are no fibers for taking up shear stresses directed transversely to the center axis of the neck.

Another known method of manufacturing orthopedic implants involves stacking fiber layers on each other to form blocks. The blocks are then machined to obtain the final geometry of the desired implant.

A known further development of this technology is an orthopetic implant which is formed of preimpregnated laminae or layers which are stacked on top of each other in accordance with the curved geometry of the desired implant. Adjacent laminae have substantially the same geometry and dependent fiber orientations since the laminae must be arranged in parallel planes. The disadvantage of this concept is the difficulty of producing complex geometries, and therefore subsequent working is necessary. During machining the fibers are damaged and the strength is reduced. Furthermore, lamination is a time-consuming process. An additional problem with this type of laminated composite is low interlaminar strength. This problem is particularly pronounced in the neck portion of the prosthesis where high interlaminar shear stresses occur.

One purpose of the present invention is to achieve a fiber-reinforced orthopedic device which does not require any subsequent work or which only requires a small amount of finishing.

Another purpose of the present invention is to achieve a fiber-reinforced orthopedic device which can be manufactured with more complicated and exact geometries.

An additional purpose of the present invention is to achieve a fiber-reinforced orthopedic device which does not have those problems with interlaminar shear stresses which occur in the known technology.

This purpose is achieved by an orthopedic load-absorbing device for implantation, said device comprising a body which is manufactured of a biocompatible fiber-reinforced polymer material and which includes a posterior side, an anterior side, a lateral side and a medial side, with a proximal portion intended to be included in a joint and a distal portion intended to be fixed in a bone, a center axis extending through the body between the outer ends of the proximal portion and the distal portion, characterized in

- that the body is made as a solid unit, composed of a plurality of separately manufactured subelements, and
- that the subelements of the body comprise fibers in a polymer matrix, said fibers in each subelement being independently oriented relative to the fibers in other subelements to give each subelement a predetermined strength property.

Furthermore, a first process is achieved for manufacture of an orthopedic load-absorbing device, which is characterized by the steps of

- manufacturing a subelement in a first mould made for the respective subelement, by arranging a fiber material with the selected fiber orientation and preimpregnated with polymer material, in the mould and applying heat and pressure over the mould to achieve a certain shape retention in the subelement, and
- arranging the subelements in a second mould with a mould cavity corresponding to the geometry of the body and causing these to be finally bonded to each other by applying heat and pressure over the second mould.

Furthermore, a second process is achieved for manufacturing an orthopedic load-absorbing device, characterized by the steps of

- manufacturing a subelement in a first mould made for the respective subelement, by arranging fibers treated with adhesive means, with selected fiber orientation in the mould, and applying heat and pressure over the mould to achieve a certain shape retention of the subelement,
- arranging the subelements in a second mould with a cavity corresponding to the geometry of the body and cohering these by applying heat and pressure over the mould, thereby achieving a certain cohesion between the subelements, and
- arranging the assembled subelements in a third mould and causing these to be finally bonded to each other by preferably adding polymer matrix in accordance with Resin Transfer Molding.

Furthermore, a third process is achieved for manufacturing an orthopedic load-absorbing which is characterized by the steps of

- manufacturing a subelement by cutting it out of a block of fiber material preimpregnated with polymer material, said block having a fiber orientation selected for the subelement, and
- arranging the subelements in a second mould and causing these to be finally bonded to each other by applying heat and pressure over the second mould or by gluing the subelements together.

Further developments of the device and processes are included in the characteristics disclosed in the subclaims.

Additional advantages beyond those already mentioned are achieved with the invention, i.a. more rapid and more simple production.

Additional advantages and characteristics will be evident from the following description.

The present invention will now be described as an example with reference to the accompanying drawings, in which:

Figure 1	is a front view of a hip implant;
Figure 2	is a side view of the hip implant in Figure 1;
Figure 3	shows the hip implant in the same view as in Figure 1 implanted in the body;
Figure 4	is a longitudinal section through the hip implant in Figure 1;
Figure 5	shows a section along the line A-A in Figure 2;
Figure 6	shows a section along the line B-B in Figure 4;
Figure 7	shows a section corresponding to the section in Figure 5 through an alternative embodiment of the hip implant;
Figure 8	shows a step in the manufacture of the device according to one embodiment of a first and a second process;

Figure 9	shows an additional step in the manufacture of the device according to one embodiment of the first and the second process; and
Figure 10	shows injection of polymer matrix in a mould by resin transfer molding according to a first embodiment of the second process.

With reference to Figs. 1 and 2, a hip joint implant 1, according to a preferred embodiment of the invention, comprises essentially a curved elongated body 2 which has a center axis 3. The body is provided with an essentially spherical head 4 which is disposed on a neck portion 7 which is joined to a curved shoulder portion 8 which in turn is joined to a somewhat conically shaped shank portion 9. Furthermore, the body is delimited by a proximal portion or joint connecting portion 5 and a distal portion or anchoring portion 6, opposing lateral and medial surfaces 10 and 11, respectively, and opposing posterior and anterior surfaces 12 and 13, respectively. The proximal portion 5 comprises essentially the neck portion 7 and is intended to be included in a ball and socket joint, in which the head arranged on the neck portion is designed to be pivotally received in a socket in the pelvis. The distal portion comprises essentially the shoulder portion 8 and the shank portion 9 and is intended to be anchored in the femur.

Fig. 3 shows how the implant is arranged in the hip. For implantation in human tissue it is suitable that the prosthesis be coated with a metallic titanium layer by ions puttering according to known technology. This metal layer is in turn covered with hydroxy apatite, also according to known technology. By virtue of the conical shape of the shank portion, the body is thereafter pressed securely against the inner walls of the bone according to what is known as macrofixation. When the prosthesis has been fixed in the bone, the bone tissue grows into the surface with hydroxy apatite, whereby so-called microfixation takes place. The natural socket in the pelvis is replaced by another implant in the form of a socket 15, in which the head 4 is received. The socket 15 is of standard type and is manufactured of a material, e.g. lathed UHMWPE (Ultra High Molecular Weight PolyEthylene) or ceramic material such as Al_2O_3, suitable for implantation and for pivotal cooperation with the head 4.

The socket is fixed by using a so-called bone cement, polymethylmethacrylate (PMMA), for example, which is polymerized during the incision itself during the hip joint operation.

Fig. 3 shows how a resultant force 16 acts on the hip joint implant. When the hip joint implant is loaded, the force 16 acts on the head 4, and this force is transmitted via the neck 7, the shoulder portion 8 and finally the shank portion 9 to the natural bone 14 of the femur. A cross-section through the implant, due to the load 16 is subjected to a bending moment, transverse forces, an axially directed compressive force and to some extent torsional forces.

Fig. 4 shows how the prosthesis is essentially constructed of a number of subelements 17-20 and 22-23, which comprise fibers in a matrix material. A subelement is characterized by extending in all dimensions by virtue of the fact that fibers are arranged in a plurality of layers or bundles which is comparable to known technology where the body is built up of layers or laminae. Furthermore, the fiber orientation in a subelement is independent of the fiber orientations of the other subelements. in contrast to laminated bodies where the fibers are oriented in parallel planes. Furthermore, the subelements are geometrically differing in shape in order to form together the total geometry of the body, in contrast to laminated bodies where adjacent layers or laminae have substantially the same geometry. The fibers in the subelements can be arranged to achieve a predetermined strength property in each of the subelements. A predetermined strength property is a strength property characteristic for the subelement, for example that the fibers are oriented so that the subelement takes up forces in certain directions better than in other directions or that the subelement takes up forces in all directions substantially equally well. Suitably. the fibers are oriented in each subelement so that essentially optical strength is obtained for the body in its intended application.

In the application in question, the subelements 18and 20 will primarily be subjected to forces in the longitudinal direction of the elements. Therefore, in this example, it is suitable that the fibers 24, which is only shown very schematically, in the subelements 18 and 20, defining opposite lateral and medial surfaces 10 and 11, respectively, are oriented in the longitudinal direction of the body. In this manner a good load-bearing capacity is obtained as regards those stresses generated by bending moment and the compressive force acting in the direction of the center axis. Furthermore, the fibers 25 in this example, which are only shown very schematically, in the subelement 19, which is arranged in the central portion of the body, oriented in planes substantially parallel to the opposite posterior and anterior sides and at an angle of approximately ±45° relative to the center axis. In this manner good load-bearing capacity is obtained with regard to the shear stresses caused by transverse forces. The fiber orientations of the subelements 18, 19 and 20 are of great importance in the proximal portion or the neck portion of the body, where the largest stresses on the body occur.

Other subelements 20 and 23, disposed essentially around the shoulder portion of the body, have fibers which are oriented in the longitudinal direction of the body as are the fibers in the elements 18 and 20.

Fig. 5 shows how the fibers 25 in the subelement 19 are arranged in layers, while the fibers 24 in the subelements 18 and 20 are shown in section perpendicular to the longitudinal direction when they are arranged in bundles in the longitudinal direction of the body.

Fig. 6 shows a section through the joint head and the neck portion. In this example, the head consists of a subelement 17 in a fiber-reinforced polymer material and which is integrated with the body. The joint head is manufactured in accordance with a process which is described in more detail below but which essentially involves rolling up a semi-elliptical fiber mat 21 in a number of layers about an axis and thereafter arranging the head thus formed on the neck portion 7. The fibers in the joint head are in this example oriented in the longitudinal direction of the body.

The head 4 can also be a separate element of another material, for example ceramic or metallic, arranged on the neck portion of the body.

Fig. 7 shows a section corresponding to the section A-A in Figure 2 through an alternative embodiment of the prosthesis. The embodiment described above has subelements stacked on each other, with subelements 1'-9' in Fig. 7 shown alternately arranged in a "bundle". There are, of course, a number of variants of the described embodiment and further conceivable embodiments, which fall within the scope of protection of the invention.

The manufacture of the previously described implant can suitably be carried out according to a first or a second process. Regardless of which process is used, there is determined initially, depending on the type of desired implant, the characteristics of the subelements which should make up the body. In a hip implant of the previously described type, it is considered at present suitable to divide the body into the previously described subelements 17-20 and 22-23. Furthermore, with regard to the forces which such an implant is subjected to, it is suitable to use the previously described fiber orientations of the subelements. For other implants another division and construction of the subelements can be more suitable and different fiber orientations can be selected.

Furthermore, a mould is manufactured for each subelement which is to be included in the body. Moreover, at least one mould is manufactured with a mould cavity for the entire body, i.e. the assembled subelements.

In one embodiment of the first process, when manufacturing the subelements, one starts with a fiber material preimpregnated with polymer material, such as prepreg or tape. The impregnation material thus forms the polymer matrix in the implant. In a first step in manufacturing, the fiber material is arranged with a selected orientation for the respective subelement.

Fig. 8 shows how a bundle of fibers 27 has been placed in a mould half 26, which is shown partially in section and which has a mould cavity intended for the subelement 20. The fiber bundle can be achieved by rolling or folding a fiber material, in the form of a fiber mat with parallel fibers, into a bundle of suitable thickness. The fibers extend in the longitudinal direction of the rolled up mat, i.e. along the mould cavity. In order to achieve subelements with varying cross-sectional areas, thicknesses and geometries, while keeping the fiber density essentially constant, it is suggested that the fiber mat have the shape of a trapezoid or a rhombus. When a fiber mat in the shape of a trapezoid is rolled up or folded perpendicular to its respective parallel sides, fiber bundles of varying cross-section area can be achieved, thus providing good fiber-filling in the entire mould cavity. It is also possible, to achieve a selected degree of fiber-filling, to place more than one fiber bundle in each mould. In this embodiment all of the subelements 18, 20, 22 and 23 have essentially parallel fibers, and therefore this method is preferable for arranging the fibers with the selected fiber direction in the moulds for these subelements.

The subelement 19 is manufactured in a somewhat different manner. The starting fiber material for this subelement is, for example, in the form of preimpregnated woven material in which the fibers are angle-oriented ±45°. Sheets are stamped out of the fiber material in accordance with the geometry of the subelement and are stacked in layers in the mould cavity. The stamping out is effected in such a way that the fibers in the body are oriented approximately ±45° in relation to the center axis and in planes parallel with the opposing posterior and anterior surfaces.

In a second step, when the fiber material has been placed in the mould cavity, heat and pressure are applied to the mould cavity for prepolymerization, and the polymer material achieves a certain shape retention in the subelement.

In a third step, the subelements thus manufactured are put together in a mould which has a mould cavity corresponding to the total geometry of the body. Fig. 9 shows a section through such a mould 29 which comprises two mould halves 30 and 31, and the body is shown in a section through the shoulder portion. Furthermore, it is shown how the separately manufactured subelements 18,19, 20, 22 and 23 are placed on top of each other in the mould cavity.

In a fourth step, heat and pressure are applied to the mould to cure or consolidate depending on whether the impregnation material is a thermosetting plastic or a thermoplastic.

In the second process for manufacturing the above described hip joint implant, according to one embodiment, the starting fiber material is not preimpregnated. Instead, the fiber material is treated with an adhesive material which can be in the form of a suitable polymer material. The first three steps in the two processes are essentially the same, the difference being that in the first process the fiber material is impregnated and in the second process the fiber material is not impregnated.

In the first step of the second process, the fiber material treated with the adhesive material is arranged with a fiber orientation selected for the respective subelement in the same manner as was described above for the respective subelements.

In the second step of the second process, when the fiber material has been placed in the mould cavity, heat and pressure are applied to the cavity, and the adhesive material achieves a certain shape retention in the subelement.

As in the first process, the subelement 19 is manufactured in a somewhat different manner. The starting fiber material in the second process for manufacturing this subelement is, for example, in the form of a woven hose, in which the fibers are angle-oriented ±45° relative to the longitudinal direction of the hose blank. The fiber material is cut in suitable lengths from the hose blank and extends along essentially the entire mould cavity when stacked therein. Furthermore, the fiber material is arranged in such a manner in the mould cavity that the longitudinal direction of the hose blank coincides with the longitudinal direction of the mould cavity and so that the fiber material in the subelement, when it is arranged in the body, is essentially oriented in a plane parallel to the opposite posterior and anterior surfaces. In order to further fix the cut hose pieces to each other it is suitable to sew them together with fiber thread.

In the third step of the second process, the subelements thus manufactured are put together in a second mould cavity corresponding to the total geometry of the body, and pressure and heat are applied to the mould to provide a body with a certain shape retention.

In the fourth step of the second process, the body is placed in a mould which is arranged to provide the polymer matrix of the body and which has a mould cavity corresponding to the geometry of the finished body. Fig. 10 shows, from above, a section through the mould 34, comprising a mould chamber or cavity 35, an inlet 32 and an outlet 33. After the body has been placed in the mould, polymer matrix is added or injected by mould injection or by resin transfer moulding (RTM) with the polymer matrix being introduced through the inlet 32 and air and surplus polymer going out through the outlet 33.

In a fifth step in the second process, the matrix is finally cured, preferably at elevated temperature.

A third, though less preferred, process comprises cutting out the respective subelement from a block of fiber-reinforced polymer material with the selected fiber orientation or in another manner working the respective subelements from such a block. In this third process, however, it is not possible in a simple manner to arrange the fibers curved in the longitudinal direction of the body. However, it is possible to see to it in a simple way that the fibers in the loaded neck portion have the desired fiber orientation by suitable cutting of the subelement from the block. If the polymer material is a thermosetting plastic, the subelements are thereafter glued together.

If the polymer material is a thermoplastic, in addition to gluing the subelements together, it is possible to continue manufacture in accordance with the first process.

It should be understood that the subelements of a body can be manufactured by combining the above described processes.

The pivot head 4 is manufactured in this example of an elongated essentially semi-elliptical fiber mat. Beginning at the minor axis, the mat is rolled up along the major axis about a shaft or a roll with dimensions corresponding to the neck portion of the body. By suitably selecting the dimensions of the fiber mat, it is wound in several layers about the shaft and forms an essentially spherical head. After the fiber mat has been wrapped up on the shaft, it is given a certain shape retention in the same manner as was described for the subelements. The pivot head 4 is then removed from the shaft or roll and slipped onto the neck portion of the body. If the fiber mat is not impregnated, the pivot head in this example is mounted on the neck before the polymer matrix is introduced. If prepreg is used, the pivot head can be arranged on the body after being manufactured separately and thereafter be consolidated further together. It is also possible to roll or wind up the fiber mat directly on the neck portion of the body.
A number of variants of the above described methods of arranging the pivot head on the body are possible, all lying within the scope of protection of the invention. In order to improve the surface properties of the pivot head in the slide surface against the socket, the surface can be coated with a metal layer, e.g. DLC (Diamond Like Coating) in accordance with known technology.

The pivot head can also be a metallic, highly polished or ceramic pivot head, made as a separate unit according to known technology. In this case, the pivot head can be arranged on the neck portion of the body in accordance with what is commonly known as a modular process, the pivot head being forced or "slipped" with good fit on the neck portion. Due to the good fit and the fact that the muscles act to contract over the joint, the pivot head is securely mounted on the neck portion of the body.

Biocompatible polymers which are used as matrix material in the present invention can essentially be referred to the groups thermosetting and thermoplastics. A particularly preferred matrix material within each respective group can, for example, be called epoxy plastics of medical quality and polyether etherketone (PEEK). Biocompatible fibers which can be used in the present invention are e.g. carbon-based, glass-based and polymer-based fibers of different types. These are well known for their strength-increasing reinforcing properties. Suitably, fiber materials are used in the form of roving, mats, woven textiles, yarn or the like. Depending on the process of manufacture, the fiber material is of non-preimpregnated or preimpregnated type. Suitably, the fiber material for the second process has been pretreated with adhesive material.

If roving is used as a fiber material, it can be placed directly in the required amount in the mould for a subelement.

In the preferred embodiment of the second process, a fiber net is slipped over the assembled subelements before injection of a polymer matrix, thus giving additional strength to the body. This can also be advantageous in the other processes in order to further improve the properties of the body.

Other fiber orientations than those described above can also be achieved in the subelements. For example, it can be advantageous to arrange the fibers crosswise in layers in the subelements. Prostheses which are subjected to other load conditions can be made simply by adapting the selection of fiber orientations in the subelements and dividing the body into subelements for expected loads.

It is also conceivable to arrange other components, e.g. a core of homogeneous biocompatible material. If the body can completely enclose other components, a greater selection of materials is available.

Other types of joints than hip joints can, of course, be manufactured with advantage according to the above described device or the above described processes. Examples of such joints can be elbow joints, knee joints and shoulder joints. For shoulder joint prostheses, for example, the distal portion is fixed to the humerus and the proximal portion is articulated in the shoulder. Furthermore, the proximal portion is not only limited for inclusion in ball and socket joints but can also be included in other types of joints, such as are present in knee joints and elbows.

In a further embodiment, the proximal portion can be anchored in another bone in the body, e.g. as splicing elements for fractured bones.

The invention is not limited to that described above or shown in the drawings but can be changed within the scope of the accompanying claims.

Claims

1. Orthopedic load-bearing device (1) for implantation, said device comprising a body (2) which is manufactured of a biocompatible fiber-reinforced polymer material and which includes a posterior side (12), an anterior side (13), a lateral side (10) and a medial side (11), with a proximal portion (5) intended to be included in a joint and a distal portion (6) intended to be fixed in a bone, a center axis (3) extending through the body between the outer ends of the proximal portion and the distal portion, **characterized** in

- that the body is made as a solid unit, composed of a plurality of separately manufactured subelements (18-20, 22, 23), and
- that the subelements of the body comprise fibers in a polymer matrix, said fibers in each subelement being independently oriented relative to the fibers in other subelements to give each subelement a predetermined strength property.

2. Device according to Claim 1, **characterized** in

- that at least one subelement (18, 20) in the proximal portion of the body has its fibers (24) oriented essentially parallel to the center axis and/or in planes substantially parallel to the sides of said at least one subelement which face the lateral or medial side.

3. Device according to one of the preceding claims, **characterized** in

- that at least one single subelement (19) has fibers (25) oriented at an angle, preferably with alternating orientations of approximately ±45°, relative to the center axis and oriented in planes substantially parallel to the anterior and posterior sides, and
- that said single subelement is arranged centrally in the proximal portion of the body.

4. Device according to one of the preceding claims, **characterized** in

- that the device is a hip joint prosthesis which comprises a curved elongated body (2) and an essentially spherically shaped pivot head (4) which is arranged on a neck portion (7) of the body, which is joined to a curved shoulder portion (8) which in turn is joined to a shank portion (9).

5. Device according to one of the preceding claims, **characterized** in

- that the lateral side and the medial side are defined by subelements (18, 20) in which the fibers are oriented substantially parallel to the center axis, and
- that subelements (22, 23) are arranged in the shoulder portion of the body, said subelements having fibers oriented substantially parallel to the center axis.

6. Device according to one of the preceding claims, **characterized** in

- that the body comprises a fiber net surrounding the subelements.

7. Device according to one of Claims 4-6, **characterized** in

- that the pivot head is formed of a rolled up semi-elliptical fiber mat in a polymer matrix.

8. Device according to one of Claims 4-6, **characterized** in

- that the pivot head is a separately manufactured component of metal or ceramic material.

9. Device according to one of the preceding claims, **characterized** in

- that the subelements are manufactured of fiber material preimpregnated with polymer material, such as prepreg.

10. Device according to one of the preceding claims, **characterized** in

- that the polymer material is a thermosetting plastic or a thermoplastic, preferably epoxy of medical quality or polyether etherketone, and
- that the fiber material is carbon-based, glass-based or polymer-based fibers.

11. Process for manufacturing an orthopedic load-bearing device according to one of Claims 1-10, **characterized** by the steps of

- manufacturing a subelement in a first mould made for the respective subelement, by arranging a fiber material with the selected fiber orientation and preimpregnated with polymer material, in the mould and applying heat and pressure over the mould to achieve a certain shape retention in the subelement, and
- arranging the subelements in a second mould with a mould cavity corresponding to the geometry of the body and causing these to be finally bonded to each other by applying heat and pressure over the second mould.

12. Process for manufacturing an orthopedic load-bearing device according to one of Claims 1-10, **characterized** by the steps of

- manufacturing a subelement in a first mould made for the respective subelement, by arranging fibers treated with adhesive means, with selected fiber orientation in the mould, and applying heat and pressure over the mould to achieve a certain shape retention of the subelement,
- arranging the subelements in a second mould with a cavity corresponding to the geometry of the body and cohering these by applying heat and pressure over the mould, thereby achieving a certain cohesion between the subelements, and
- arranging the assembled subelements in a third mould and causing these to be finally bonded to each other by preferably adding polymer matrix in accordance with Resin Transfer Molding.

13. Process for manufacturing an orthopedic load-bearing device according to one of Claims 1-10, **characterized** by the steps of

- manufacturing a subelement by cutting it out of a block of fiber material preimpregnated with polymer material, said block having a fiber orientation selected for the subelement, and
- arranging the subelements in a second mould and causing these to be finally bonded to each other by applying heat and pressure over the second mould or by gluing the subelements together.

14. Process according to Claims 11, 12 or 13, **characterized** by

- orienting, in at least one subelement, the fibers so that they are arranged, in the proximal portion of the body, essentially parallel to the center axis and/or in planes substantially parallel to the sides of said at least one subelement which face the lateral or medial side.

15. Process according to Claims 11, 12, 13 or 14, **characterized** by

- arranging the fibers in at least one single subelement so that they are oriented in the body at an angle, preferably alternatingly oriented approximately ±45°, relative to the center axis and oriented in planes substantially parallel to the anterior and posterior sides, and
- arranging said single subelement centrally in the proximal portion of the body.

16. Process according to one of Claims 11-15, **characterized** in

- that a fiber net is slipped over the assembled subelements.

17. Process according to one of Claims 11-16, **characterized** by

- rolling up a semi-elliptical fiber mat along its major axis on a cylindrical element or directly on the proximal portion to form an essentially spherical pivot head, and
- arranging the pivot head on the proximal portion of the body.

18. Process according to one of Claims 11-16, **characterized** by

- arranging a pivot head of metallic or ceramic material on the proximal portion of the body.

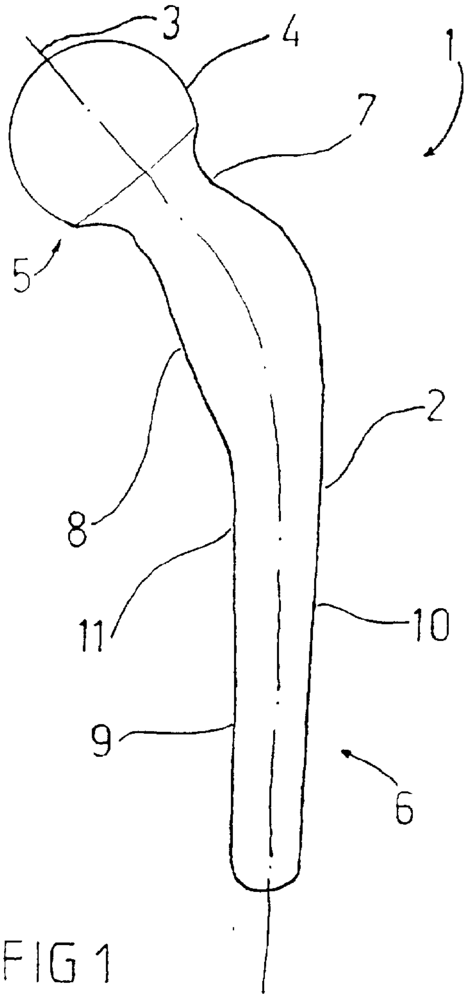

FIG 1

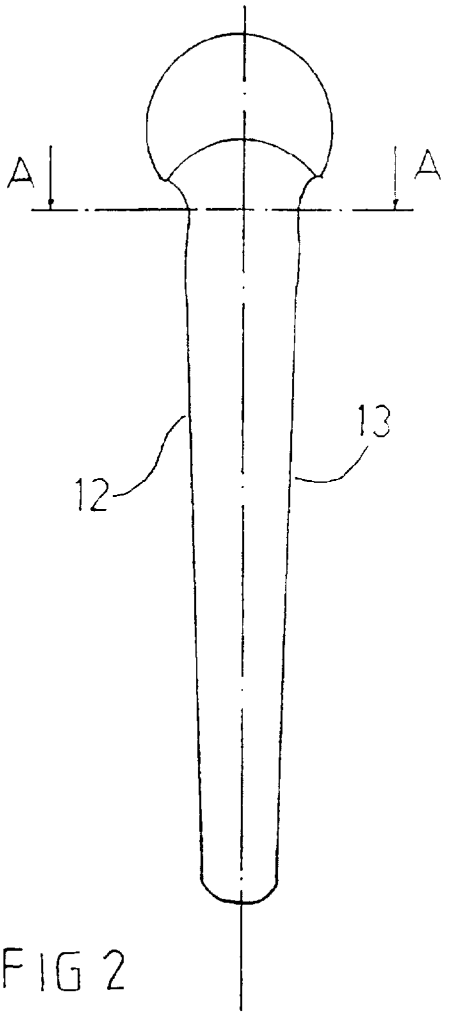

FIG 2

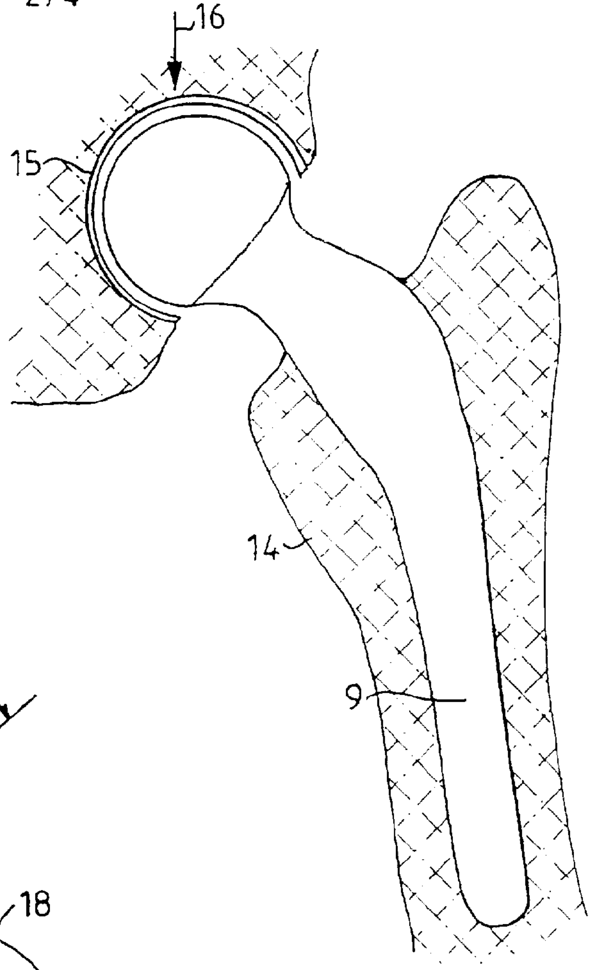

FIG.3

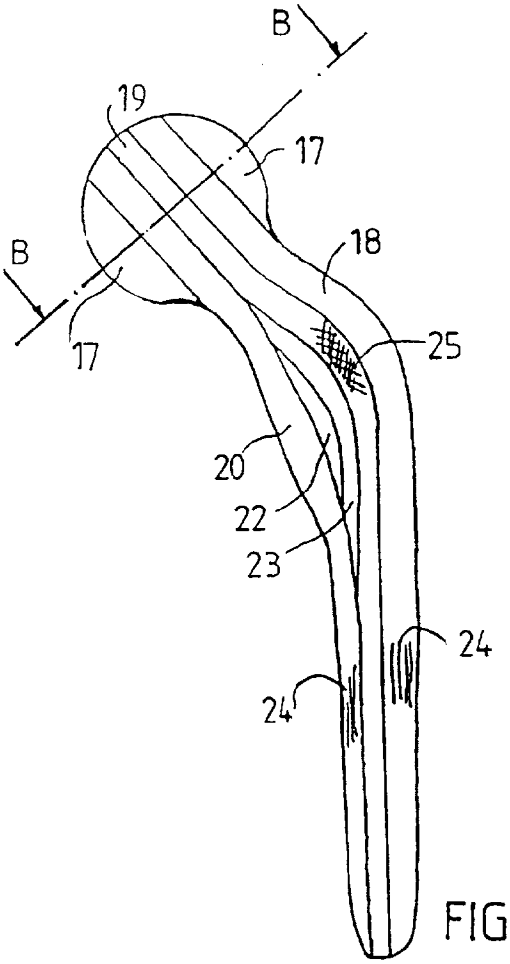

FIG. 4

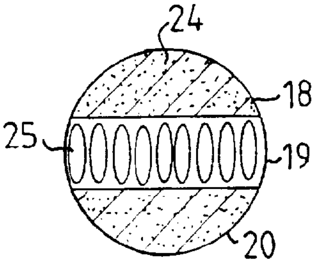

FIG. 5

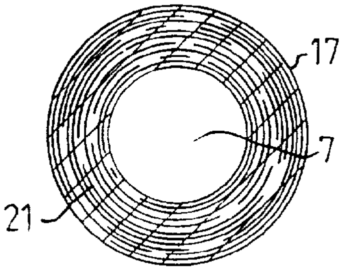

FIG.6

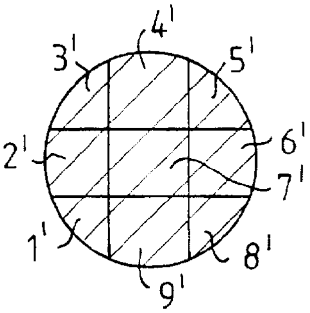

FIG. 7

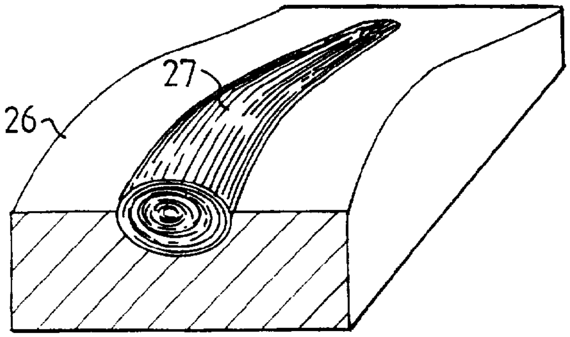

FIG.8

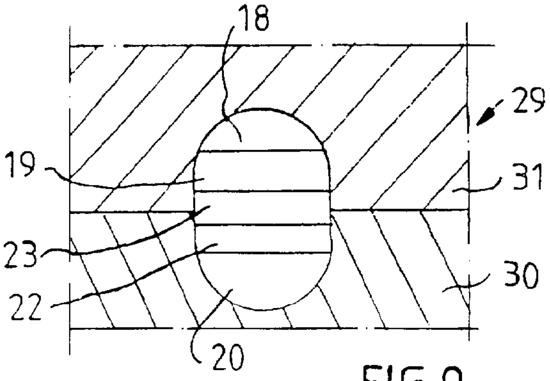

FIG.9

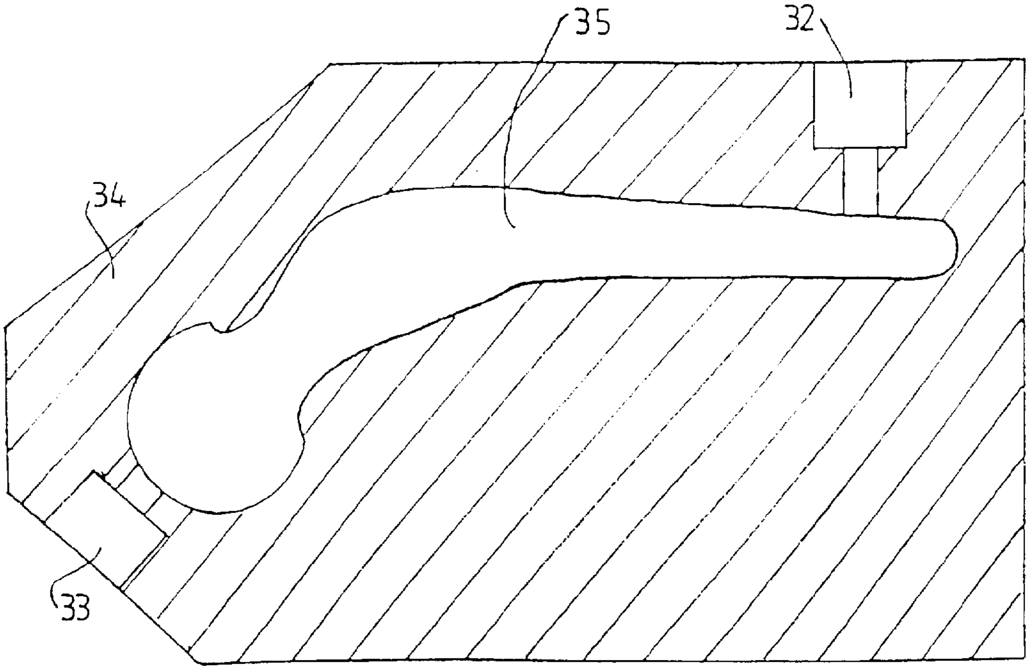

FIG.10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 97/01597

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/28, A61F 2/32 // A 61 L 27/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 3243861 A1 (M.A.N. MASCHINENFABRIK AUGSBURG-NüRNBERG AG), 13 October 1983 (13.10.83), page 8, line 17 - line 21, figure 3 --	1-5,8,10, 13-14,18
Y	US 5141521 A (ULRICH WENNER), 25 August 1992 (25.08.92), figure 1, abstract --	1-5,8,10, 13-14,18
A	Derwent's abstract, No 95-104682/14, week 9514, ABSTRACT OF SU, 4907532 (KOMPOSIT SCI PRODN ASSOC), 1 February 1991 (01.02.91) --	1-2,4-5, 10-14
A	US 4266302 A (ALAIN TORNIER), 12 May 1981 (12.05.81) --	1-2,4-5,10

☒ Further documents are listed in the continuation of Box C.　☒ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

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"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 7 March 1998	Date of mailing of the international search report 11 -03- 1998
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 97/01597

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5181930 A (JOHN H. DUMBLETON ET AL.), 26 January 1993 (26.01.93), figures 1-2, abstract	1-2,4-6, 10-14,16
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INTERNATIONAL SEARCH REPORT

Information on patent family members

03/02/98

International application No.

PCT/SE 97/01597

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		WO 9218068 A	29/10/92